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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,765	01/05/2004	Pierluca Lombardi	GUID-134	2275
89729	7590	01/31/2011	EXAMINER	
Law Office of Alan W. Cannon			GILBERT, ANDREW M	
942 Mesa Oak Court				
Sunnyvale, CA 94086			ART UNIT	PAPER NUMBER
			3767	
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			01/31/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/751,765	LOMBARDI, PIERLUCA
	<b>Examiner</b>	<b>Art Unit</b>
	ANDREW M. GILBERT	3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 July 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13, 15, 16, 18-21 and 23-30 is/are pending in the application.  
 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.  
 5) Claim(s) 21, 23 and 26-28 is/are allowed.  
 6) Claim(s) 13, 15, 16, 24, 25, 29 and 30 is/are rejected.  
 7) Claim(s) 18 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 05 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/15/2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 11/15/2010.
2. In the reply, the Applicant amended claims 13 and added new claims 29-30. Claims 19-20 were previously withdrawn.
3. Thus, claims 13, 15-16, 18, 21, 23-30 are pending for examination.

### ***Claim Objections***

4. Claim 13 objected to because of the following informalities: Claim 13 recites “said at least one of said discrete threshold setting features”. Appropriate correction is required. The examiner believes the limitation should read “~~said~~ at least one of said discrete threshold setting features”. It reads clearer.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13 recites “discrete threshold setting features” and a “user manually contacting ... at least one of said discrete threshold setting features to perform manual selection, by said manual manipulation of said

feature of said valve, of a discrete, pre-set threshold pressure level..." First, It is unclear what "said feature of said valve" is reciting. Second, the applicant's original specification discloses manually positioning the orifice (28) via moving the selector member (50) to select the discrete threshold pressure level. However, the user does not manually contact "at least one discrete threshold setting features" (which the examiner believes the plurality of openings (44, 46, 48), rather the user contacts the one selector member (50). The user does not manually contact the plurality of openings. Thus, the recitation of the user manually contacting at least one of said discrete threshold setting features is not disclosed in the specification. Further, the examiner suggests clarifying "said feature" in Ins 16-17 of claim 13. The Examiner believes this element is attempting to reference the selector member (50) of the applicant's invention, but it is currently unclear.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 recites the limitation "said feature" in In 16-17. There is insufficient antecedent basis for this limitation in the claim. The applicant has previously recited "discrete threshold setting features" but not "said feature."

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Treu (5630935). Treu discloses an apparatus for regulating pressure applied during a medical procedure, comprising: a housing enclosing an inner volume for conveying a pressurized fluid, the housing comprising a substantially inelastic housing enclosing the inner volume and a plunger movable within the inelastic housing for applying pressure to the inner volume (syringe shown as 135; Fig 4a); and a pressure-operated-valve (78) in fluid communication with the inner volume of the housing (Fig 4a) and adapted to release pressure from the inner volume when fluid pressure in the inner volume is exerted on the pressure operated valve above a threshold fluid pressure level, wherein the pressure-operated valve is provided with at least one opening (Fig 4a) and a selector member (130) positionable by a user, relative to said at least one opening, to select the threshold fluid pressure level (col 9, Ins 56-67).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 13, 15-16, 24-25, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (4623335) in view of Woodworth et al (4550747). Jackson discloses an apparatus for regulating pressure applied during a medical procedure, comprising: an cylindrical inelastic housing (24) enclosing an inner volume, the

cylindrical housing having a first and second end (respective end of syringe 24 and end that contacts the needle portion 12, 30) forming said cylindrical housing; and a plunger (25) for applying pressure to the inner volume and being slidably disposed within the inelastic housing (Fig 1); an aperture (distal opening of 26 that is in fluid communication with the needle 12) in the housing for conveying pressure from the housing during medical procedure, and a pressure-operated valve (22; Fig 2) coupled between the inner volume of the housing and a space outside of the inner volume of the housing for allowing pressure to escape from the inner volume of the housing through the valve when pressure in the housing exceeds a threshold, whereby the valve releases pressure from within the inner volume of the housing (Figs 1-4; col 5, lns 32-col 6, lns 3); wherein the pressure operate valve comprises and opening (68), a plunger (44) disposed within the inner volume of the housing; a spring (52) disposed within the inner volume of the housing, wherein the spring is positioned between the second end of the housing and the plunger (Fig 2), wherein the plunger in a rest position is between the opening and the aperture (Fig 2), and wherein as fluid is inserted into the inner volume of the housing via the aperture, increased pressure within the inner volume of the housing moves the plunger toward the opening (Figs 1-4; col 5, lns 32-col 6, lns 3); wherein the opening is positioned in a side of the housing providing access to the inner volume of the housing (68; Fig 2), wherein at normal pressure the opening is closer to the second end than the plunger and wherein as pressure within the inner volume of the housing increases so as to move the plunger past the opening (Figs 1-4), the pressure within the inner housing is released through the opening (Figs 1-4; col 5, lns 32-col 6,

Ins 3); wherein the threshold is set by a spring exerting a force which must be overcome to exceed the threshold (Figs 1-4; col 5, Ins 32-col 6, Ins 3).

7. However, Jackson does not disclose that the pressure operated valve is adapted to allow manual selection of the threshold, during use, from a plurality of different pre-set thresholds by manually contacting said at least one discrete threshold setting feature to perform manual selection by manual contact, wherein the threshold pressure levels intermediate of two of any of said discrete, pre-set threshold pressure levels cannot be selected; wherein a movable member which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold.

8. Woodworth et al teaches that it is known to have a pressure operated valve adapted to allow selection of the threshold during use from a plurality of different thresholds (Summary; col 1, Ins 11-15; col 5, Ins 60-67) by manually contacting said apparatus to perform manual selection by manual contact (Summary; col 1, Ins 11-15; col 5, Ins 60-67; the user Manually controls the force by manual user input into a computer controlled pressure relief valve. The force values are manually entered by the user into the computer controlled system); wherein the threshold pressure levels intermediate of two of any of said discrete, pre-set threshold pressure levels cannot be selected (Summary; col 1, Ins 11-15), wherein the user controls the force and thus the threshold via the adjustment member and a movable member (piston) which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold (Summary; col 1, Ins 11-15;

col 5, Ins 60-67) for the purpose of having a user set computer controlled pressure relief valve with improved accuracy over more than one user set discrete pressure value. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spring system as taught by Jackson with the having spring system, piston, and a user set computer controlled pressure relief valve as taught by Woodworth et al for the purpose of having a user set computer controlled pressure relief valve with improved accuracy over more than one user set discrete pressure value.

***Allowable Subject Matter***

1. Claims 21, 23, 26, 27, 28 are allowed.
2. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

3. Applicant's arguments filed 11/15/2010 have been fully considered but they are not persuasive.
4. The applicant argues that Woodworth et al is not analogous art and does not disclose manual selection.
5. The Examiner disagrees. Woodworth et al is analogous art because it relates to controlling pressure within a system via a pressure relief valve and relieving pressure at a threshold set by a user by a computer control system. In Woodworth et al a user teaches that it is known to have a pressure operated valve adapted to allow selection of the threshold during use from a plurality of different thresholds (Summary; col 1, Ins 11-

15; col 5, lns 60-67) by manually contacting said apparatus to perform manual selection by manual contact (Summary; col 1, lns 11-15; col 5, lns 60-67). The user manually controls the force by manual user input into a computer controlled pressure relief valve. The input keys are the at least one discrete threshold setting feature. The force values are manually entered by the user into the computer controlled system. Thus, Woodworth teaches manually contacting the apparatus to perform a manual selection by manual contact by the user of a programmable computer or host controller. The rejection is maintained.

6. The Examiner suggests structurally defining how the user manually manipulates the features of the valve to distinguish the applicant's invention from a user manually inputting a threshold value into a computer system.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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